

1 continue to provide our overseas customers with
2 the assurance that U.S. agricultural products
3 are safe and free from BSE.

4 I'm very concerned about the
5 enforcement of this regulation with our
6 surveillance at our ports and our borders, and I
7 believe that most important -- excuse me, and I
8 believe that more effort and resources must be
9 provided toward making certain that the
10 firewalls can prevent feeding ruminant proteins
11 to ruminants and which would prevent the entry
12 of BSE into our food chain were BSE to occur
13 must be supported by significantly improved
14 oversight by the FDA.

15 On behalf of our employees, I
16 take this opportunity to thank you for the
17 opportunity to provide this statement today and
18 for the FDA's efforts to keep the United States
19 BSE-free.

20 DR. LUMPKIN: Thank you,
21 Mr. Smith.

22 Any questions from members of
23 the panel?

24 (No response.)

25 DR. LUMPKIN: Thank you again.

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1 The next speaker is Dr. Gary
2 Pearl. He is president and director of
3 technical services with the Fats and Proteins
4 Research Foundation of Bloomington, Illinois.

5 DR. PEARL: Thank you. This
6 opportunity to offer comments to the Food and
7 Drug Administration solicitation of information
8 pertaining to its animal feeding regulation as
9 referenced in the Federal Register October 5,
10 2001, Volume 66, Number 194, is very much
11 appreciated. These comments are being made on
12 behalf of the Fats and Proteins Research
13 Foundation.

14 FPRS is organized to serve the
15 rendering and its associated industries. The
16 rendering function is that of recycling the
17 co-products resulting from food animal
18 production. The rendering and its ancillary
19 support industry has ecologically, economically
20 and via the most biosecure procedure processed
21 the more than 50 billion pounds of inedible
22 animal tissue generated annually into products
23 of value for a variety of useful purposes.

24 Rendering represents the
25 collection of animal raw materials from

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1 slaughter, from packing, from processing, food
2 preparation and fallen animal sites for
3 transport to process controlled facilities,
4 heated to a temperature higher than that
5 required for sterilization and removes the
6 moisture, a process not afforded by any other
7 permissible alternative. The fat is extracted
8 from the protein and the fat and protein are
9 then used as animal feed ingredients or for
10 other important industrial uses.

11 FPRF was organized in 1962 to
12 provide an institution which will direct and
13 manage a research process that results in an
14 enhanced current usage and the development of
15 new uses for rendered animal products in a
16 biosecure methodology. FPRF is a nonprofit,
17 nonlobbying organization, as defined by Illinois
18 statutes. Approximately 100 industry members
19 voluntarily support and contribute in a
20 cooperative effort to focus research resources
21 to the individual research projects. Over 125
22 projects have been assigned and completed since
23 1994, and all of these projects and their
24 researchers are strongly encouraged to publish
25 the results in peer reviewed journals with

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1 nearly 90 percent of the projects resulting in
2 published or for public knowledge usage.

3 Though there were 17 specific
4 questions posed in the October 5th, 2001,
5 document. These comments will not address each
6 question directly, but such will be supplied
7 within the written comment period to follow.

8 The 21 CFR 589.2000 regulation
9 has functioned within its objectives to prevent
10 the establishment or the amplification of the
11 infectious agent, the bovine spongiform
12 encephalopathy, to the U.S. cattle population.
13 Thus, in a composite review of the questions,
14 there is little need to duplicate the process
15 initiated 1996 and resulting in the August 1997
16 prohibition of specified animal proteins in
17 ruminant feed. The specifics of that
18 prohibition incorporated the best scientific
19 information available, but it interpreted that
20 information by instilling a degree of cautionary
21 principle as added safety, even while knowing of
22 the BSE-free status in the U.S. as validated by
23 extensive testing.

24 The intensive compliance
25 accompanying the establishment of the rule has



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1 now been supplemented with the development and
2 implementation of third-party certification
3 programs. Of importance are those of the APPI
4 organization supervised or completed by Cooke
5 and Thurber directed at the rendering industry,
6 and the facility certification institute at the
7 feed manufacturing industry. Both have resulted
8 in validation of facilities that produce a very
9 high percentage of all animal proteins and feed
10 manufacturers producing a significant tonnage of
11 all the mixed feeds. These and other voluntary
12 actions have been taken to ensure compliance
13 with government regulations, while demonstrating
14 an active commitment to the feed and food safety
15 in the animal health, public health sector.

16 Surveillance initiatives and
17 numerous associative regulations initiated in
18 1986 and enhanced throughout this subsequent
19 15-year period have provided no evidence that an
20 enhanced risk for the emergence of BSE has been
21 altered. This foundation has been promoting the
22 research attention to the identified priorities
23 established by the agency and referenced in the
24 August 1997 regulation. Among those were
25 inactivation of the causative agent,

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1 transmission among inter and intra species,
2 diagnosis with emphasis on preclinical
3 procedures, detection procedures for individual
4 species protein in meat and ingredients and
5 feed, and the epidemiology of the respective
6 TSEs.

7 With the recognition of
8 fragmentary research contributions filling a few
9 voids, in composite most of the outlying
10 priorities still remain. They remain without
11 conclusive answers. These priorities were
12 essentially restated in the summary comments
13 resulting from a USDA/ARS BSE workshop held
14 March 15, 2001. There is not sufficient
15 scientific evidence to alter the regulatory plan
16 that was established, initiated and validated
17 for compliance as outlined in the final rule of
18 August 1997.

19 Additionally, this foundation
20 has, since its inception, retained a focus on
21 the biosecurity principles provided by the
22 rendering procedures. Recent validation that
23 proper time/temperature processing inactivates
24 viral and primary foodborne pathogens -- and I
25 name in specific Salmonella species, Listeria

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1 monocytogenesis, Clostridium perfringens and
2 Campylobacteria jejuni -- in by-products derived
3 from slaughter of animals for food purposes.
4 This assurance is not available for the other
5 alternatives for rendering and certainly becomes
6 increasingly important as we face new
7 biosecurity challenges of today.

8 Animal agriculture has, and now
9 more than ever, depends upon the sanitary,
10 biological secure, ecological and environmental
11 processing and the infrastructure of the
12 rendering industry as a vital synergistic means
13 of utilizing approximately one-half of all
14 livestock and poultry tonnage produced in the
15 U.S. each year.

16 In summary, the 21 CFR 589.2000
17 rule instituted as a firewall regulatory adjunct
18 to a series of precautionary practices is not in
19 need of any extensive modifications or changes
20 until which time science and research findings
21 dictate.

22 Thank you again for this
23 opportunity.

24 DR. LUMPKIN: Thank you,
25 Dr. Pearl.

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1 Any questions?

2 (No response.)

3 DR. LUMPKIN: Thank you, sir.

4 The final speaker of the
5 morning before we take our lunch break will be
6 Richard Sellers. He is vice president of feed
7 control and nutrition of the American Feed
8 Industry Association in Arlington, Virginia.

9 MR. SELLERS: Thank you
10 Dr. Lumpkin.

11 The American Feed Industry
12 Association is the national feed trade
13 association representing feed manufacturers,
14 ingredient suppliers, equipment manufacturers,
15 pet food manufacturers, animal health
16 manufacturers, and distributors and other
17 suppliers to the feed industry. AFIA members
18 manufacture 75 percent of the primary commercial
19 feed in the United States. Therefore, our
20 members are affected by these regulations, and I
21 present these comments on their behalf. More
22 thorough comments will be provided to the docket
23 prior to November 21st.

24 We appreciate the agency
25 offering this opportunity to review the rule and



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1 make comments on the current issue, state of
2 science of transmissible spongiform
3 encephalopathies, or TSEs. Only by collecting
4 comments and information can the U.S. have the
5 best prevention program. In fact, AFIA believes
6 the risk of BSE in the United States is near
7 zero and that the vigilance and attention to
8 detail by our government and the industry have
9 resulted in keeping the U.S. BSE-free for over
10 16 years.

11 The three firewalls mentioned
12 by speakers today are very important. And AFIA
13 pledges its continued commitment for compliance
14 to the second firewall, which is the feed rule.
15 We continue to support the FDA's hundred percent
16 inspections and believe our continued efforts to
17 educate the industry about compliance with this
18 rule is the best risk reduction effort we can
19 take. In fact, the Facility Certification
20 Institute, which was created by AFIA as an
21 independent third-party inspection system, is
22 very much an educational program designed to
23 certify facilities' compliance with this rule.

24 AFIA believes the top
25 enforcement priority of the agency should be

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1 education, followed by aggressive action against
2 any firm or individual knowingly feeding
3 prohibited protein to ruminants or distributing
4 such material for that use.

5 The final rule is basically a
6 labeling and recordkeeping rule, and compliance
7 in the latter area of recordkeeping has been
8 nearly perfect. We believe the labeling
9 compliance is more complicated than the
10 inspection numbers released by the agency. We
11 have met with agency officials to express our
12 concerns about the inspection form and
13 inspection reporting. We fully support CVM's
14 effort to fully clarify the compliance issues in
15 its efforts to reduce subjectivity in the
16 inspection form.

17 AFIA has taken an active role
18 in promoting inspection and compliance with the
19 states and seeking funding for them where
20 appropriate. We believe all states should be,
21 and many are, active partners in achieving full
22 compliance with this rule. We urge FDA to fully
23 fund these state inspections where appropriate.

24 With respect to the adequacy of
25 the current rule, AFIA believes the rule is

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1 adequate and further education and compliance
2 efforts are the most important effective way of
3 reducing risk of BSE coming to the United
4 States. Such a continued, sustained effort
5 would likely be far more effective in reducing
6 risk than any changes to the current rule. We
7 believe the exemptions in the rule are still
8 scientifically justified; however, there needs
9 to be a regular revisiting of the rule to
10 strengthen it if new risks are identified or to
11 remove restrictions if no longer justified by
12 the scientific assessment of risk.

13 AFIA believes that neither
14 dedicated facilities nor vehicles will preclude
15 all risk. We need full compliance with the
16 current rule, which is dependent on continued
17 extensive education and appropriate enforcement
18 actions. AFIA acknowledges that commingling
19 incidents have occurred in the United States.
20 They have been small in number and many are of
21 minor consequence. This low incidence is
22 evidence of the industry's commitment to
23 maintaining a BSE-free United States.

24 Regarding licensing of firms to
25 utilize prohibited protein, AFIA believes this

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1 would detract from the already limited funds to
2 enforce the current rule. Licensing firms would
3 rob the resources for the more important
4 activities of education and compliance.

5 AFIA strongly supports the
6 current cautionary labeling statement and does
7 not believe that pet foods, except salvage pet
8 foods, should be labeled with the statement.
9 This would confuse consumers, as FDA agreed in
10 the 1997 rules preamble. Again, FDA should
11 place its efforts in educating the salvage
12 dealers in gaining compliance using measured
13 enforcement.

14 The recordkeeping provisions in
15 the current rule are required to document
16 compliance with the rule. The long latency
17 period for this disease would require
18 considerable record retention for investigatory
19 purposes. The cost benefit of such a longer
20 time is very high, as little is gained from
21 maintaining records for five to ten years.
22 Again, education and compliance with the rule
23 should be the principal way of reducing risk.
24 The agency's rationale for one-year record
25 retention is as valid now as it was in 1997.

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1 Some might request the agency
2 change the ingredient listing to require
3 species-specific listings. This is a very
4 costly undertaking and would be a reverse step
5 to the 30 years of acceptance and use of
6 collective terms. And I might add as
7 nutritionist, there are no requirements for
8 ingredients; there requirements for nutrients
9 that may be supplied by a number of ingredients.
10 A much easier tasks is to look for the
11 cautionary statement required for products
12 containing restricted use protein products. The
13 statement should be a clear and prominent one,
14 and one that assists the producer in assuring
15 compliance.

16 As indicated earlier, the
17 current cautionary statement is adequate. We
18 believe farmers have a clear understanding of
19 the term "ruminant." AFAI is clearly in favor
20 of a continued education campaign which will
21 likely prove more effective in accomplishing the
22 intended protection than expanding the
23 cautionary statement.

24 AFIA believes the industry
25 definitely needs test methodology that is both

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1 sensitive and specific in order to ensure
2 compliance and investigate illegal activities.

3 Also we believe false positive
4 tests increase the perception of violations. So
5 we support the continued effort for research in
6 this area. As mentioned earlier, AFIA created
7 the Facility Certification Institute to further
8 educate the industry and certify compliance with
9 this rule. AFIA and FCI believe the agency
10 should demonstrate strong support for this
11 effort. The Facility Certification Institute
12 filed a draft partnership agreement with FDA
13 yesterday to further enhance FCI's efforts and
14 to recognize the unique nature of a potential
15 formal relationship of the two organizations.
16 This partnership would allow recognition of FCI
17 certification by FDA and would encourage FDA to
18 shift inspection resources from certified
19 facilities to other compliance and educational
20 efforts designed to reduce the risk of BSE in
21 the United States.

22 AFIA is concerned about the
23 potential for the introduction of BSE into the
24 U.S. via imports. The current inspection
25 process for imports is not adequate, and more

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1 funds should be directed to preclude the entry
2 of restricted products. There is a real need
3 for the agency to further strengthen this first
4 important firewall.

5 AFI believes, finally, that the
6 agency has been diligent in carrying out its
7 responsibilities commensurate with reducing the
8 risk of BSE being established and amplified in
9 the United States. However, the
10 Administration's support lagged during the
11 two-year period of 1999 to 2000 as states were
12 unable to secure complete funding for
13 investigation and the number of inspections were
14 reduced from the first two years. Only after a
15 series of negative media articles appeared
16 earlier in this year did more funds and
17 resources materialize to finish with a new
18 commitment to finish all the inspections. This
19 commitment was made 1997 to finish the
20 inspections within the first two years, but
21 resources appear to have been moved to cover
22 other hot agency topics.

23 The see-saw commitment to the
24 inspection program is unfortunate and
25 unwarranted for an industry which has cooperated

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1 with the agency on an ongoing, constant basis
2 for four years. We need these inspection
3 resources. The American people deserve nothing
4 less than the agency's full commitment to
5 preventing this devastating disease from
6 entering the U.S.

7 We pledge our continuing
8 commitment to a goal of 100 percent inspections,
9 100 percent compliance, and assuring the
10 federal/state agencies have the necessary
11 resources to make that happen.

12 I thank you for the opportunity
13 to submit these comments, and I look forward to
14 continuing our education and compliance
15 efforts.

16 DR. LUMPKIN: Thank you,
17 Mr. Sellers.

18 Are any questions?

19 DR. SUNDLOF: Richard, you
20 mentioned that enforcement of those that
21 knowingly violate the regulations. Do you think
22 that continued effort is necessary to maintain
23 education for those that are not fully aware of
24 the regulations in place?

25 MR. SELLERS: I do believe that

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1 there is a continuing education effort that's
2 needed in light of the hundreds of millions of
3 dollars of regulations that we have to deal with
4 from other federal and state agencies. And it's
5 important on an ongoing basis to keep this issue
6 in front. We try to do that with our industry,
7 but there are other -- biosecurity, other
8 pressing things that keep coming out. We sent a
9 number of our videotapes and a number of your
10 compliance guides and our compliance guides when
11 requested. And one of the actions of AFIA is an
12 educational effort to provide those compliance
13 documents actually on a different inspection
14 level, on a higher inspection level than the
15 agency practices.

16 DR. SUNDLOF: Thank you.

17 DR. LUMPKIN: Thank you.

18 One quick announcement before
19 lunch. As many of you are aware, Billy Ray
20 Smith is the Commissioner of Agriculture of the
21 Commonwealth of Kentucky. He is also the
22 occurrence NASDA president. Unfortunately, he
23 could not be with us today but he did send a
24 representative, a Dr. Chris Young, as one of the
25 state representatives. He is standing in the

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1 back. In introduced the other state
2 representatives earlier, and he joined us at
3 later this morning. So I wanted to make sure I
4 had a chance to introduce him and thank him for
5 being here and representing Commissioner Smith.

6 With that, let us adjourn for
7 lunch. And as per the agenda, we will reconvene
8 at 1:15 in this room.

9 Thanks much.

10 (The luncheon recess was
11 taken.)

12 DR. LUMPKIN: It's now 1:15.
13 I'd like to reopen the afternoon session of this
14 public hearing.

15 I have one announcement. If
16 there's is Mr. Ernie Parker in the audience, he
17 needs to call his office. That's Ernie Parker.
18 He needs to call his office.

19 The first group of speakers
20 that will be speaking are going to be
21 representing the National Grain and Feed
22 Association. It's my understanding there's
23 going to be a tag team approach here between
24 1:15 and 1:30. The speakers will be Mr. Joseph
25 Garber from Wenger's Feed Mill, Inc., in Rheems,

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1 Pennsylvania, and Brad Gottula from the Land O'
2 Lakes Feed in Fort Dodge, Iowa.

3 I think this is Mr. Garber; is
4 that right?

5 MR. GARBER: That's right.
6 Good afternoon.

7 The National Grain and Feed
8 Association welcomes this opportunity to provide
9 its thoughts to the Food and Drug
10 Administration's current animal feeding
11 regulations designed to keep the United States
12 free of BSE.

13 I am Joe Garber, chairman of
14 the NGFA's feed industry committee. I am the
15 nutrition and research coordinator for Wenger's
16 Feed Mill, Inc., in Rheems, Pennsylvania. Also
17 presenting a portion of this testimony will be
18 Brad Gottula, chairman of the NGFA Feed Industry
19 Committee's Legislative and Regulatory Affairs
20 Subcommittee, as well as chairman of our Animal
21 Protein Transportation Task Force. Mr. Gottula
22 is the director of quality assurance and
23 regulatory compliance for the Land O' Lakes
24 Farmland Feed, LLC, in Fort Dodge, Iowa.

25 Established in 1986, the NGFA



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1 is a nonprofit trade association of more than
2 1,000 grain, feed and processing facilities and
3 other grain-related firms. Our members operate
4 more than 5,000 facilities and handle more than
5 two-thirds of U.S. grain and oilseeds. In
6 addition to our oral statement, we also will be
7 submitting a written statement for the official
8 record for this rulemaking.

9 We commend FDA for initiating
10 this rulemaking to review its current BSE
11 prevention regulations. As it does so, we
12 believe it is of paramount importance for FDA to
13 continue to base its decisionmaking on the best
14 available science and prudent risk assessment.
15 The entire world is looking to FDA as a model
16 agency for prudent science-based risk
17 assessment. To deviate from that sound course
18 would undermine the agency's moral authority for
19 regulating food and feed safety. Were that to
20 occur, we would likely see the emergence of a
21 hodgepodge of different state laws and
22 regulations to address BSE and an undermining of
23 consumer confidence.

24 We also believe FDA should
25 review its rule from the perspective that not a



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1 single case of BSE has been detected in the
2 United States. Since 1990 that is viewed as the
3 most extensive of any country in the world, with
4 the exception of Europe, where the BSE agent
5 does exist.

6 This is attributable in large
7 part to an effective and science-based triple
8 firewall strategy implemented by the government
9 that the NGFA strongly supports. Those
10 firewalls consist of import bans, a prohibition
11 on feeding specified mammalian proteins to
12 cattle and other ruminant animals and active
13 surveillance and inspection programs.

14 The NGFA has adopted a BSA
15 prevention policy that pledges our firm
16 commitment to science-based BSE prevention
17 measures. We recognize that science is not
18 static and that the agency and industry have a
19 responsibility to base future decisions on the
20 best available facts that exist.

21 But based on our understanding
22 of the current science related to BSE, the NGFA
23 fully supports the FDA's existing regulations
24 and does not believe that the current ban on
25 feeding certain mammalian proteins to ruminant

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1 animals should be expanded beyond the
2 restrictions now in place. We support the
3 continued use of ruminant-derived protein as a
4 safe, nutritious and wholesome feed ingredient
5 for species for which it is legally approved.

6 With this groundwork laid, we
7 now would like to respond to several of the
8 major questions posed by FDA in its October 5
9 Federal Register notice. We have organized our
10 responses to FDA's questions into three broad
11 areas: The scope of the feeding restrictions,
12 enforcement and compliance-related issues, and,
13 as Mr. Gottula will address, operational issues.

14 First concerning the scope of
15 the feeding restrictions. We believe the
16 current FDA rule is adequate to meet the stated
17 objective of preventing the spread through feed
18 of the BSE agent if it were ever to enter the
19 United States.

20 Rather than broadening the
21 rule's objectives, we believe the first order of
22 business is to achieve as close to 100 percent
23 compliance with the existing rule, particularly
24 among multi-species feed mills that manufacture
25 ruminant feed and handle prohibited mammalian

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1 protein. The NGFA does not believe FDA feeding
2 restrictions should be broadened to include
3 other mammalian proteins unless there's
4 compelling scientific evidence that the
5 ingredient is a vector of the BSE agent.

6 For the same science-based
7 reasoning, we also do not believe FDA should
8 revoke or change the exclusions for certain
9 products allowed in the current rule, nor should
10 the agency add to the list of mammalian proteins
11 that are restricted from being used in feed for
12 cattle or other ruminants.

13 Second, FDA poses several
14 enforcement and compliance-related questions.
15 The NGFA believes that the existing authorities
16 at both the federal and state level, including
17 the states' authorities, to issue stop-sale
18 orders, are strong and effective tools to ensure
19 compliance. We believe a visible surveillance
20 presence by FDA and states is more important to
21 encouraging compliance than additional
22 enforcement authorities.

23 Concerning future enforcement
24 activities, the NGFA recommends strongly that if
25 FDA and state partners adopt a more targeted



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1 inspection and enforcement plan in the future.
2 We believe the central component of such a plan
3 will be a trace-forward approach in which the
4 movement and use of ruminant-prohibited
5 mammalian protein is tracked from the source to
6 subsequent receivers.

7 We recommend this be
8 accomplished through the development of a
9 statistically valid, random inspection program.
10 We believe this should be augmented by states
11 conducting BSE rule compliance inspections as
12 part of their routine feed mill inspections and
13 commend the Association of American Feed Control
14 officials for including that component in its
15 BSE policy statement.

16 In joint meetings with other
17 animal industry, feed and rendering
18 organizations, we believe it is an emerging
19 consensus that a traceable approach makes sense
20 from a risk assessment and resource allocation
21 basis. As part of such an approach, the NGFA
22 recommends that FDA develop an overall strategic
23 plan to guide its future BSE prevention
24 surveillance and inspection efforts.

25 From an inspection standpoint,



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1 we believe FDA's first priority should be
2 facilities that manufacture feeds for ruminants
3 and other species and which handle prohibited
4 mammalian protein. Surveillance should also be
5 focused on direct purchasers of prohibited
6 mammalian protein as well as salvage feed or pet
7 food to ensure that the product is being
8 inspected and sold to the appropriate channels.

9 Of secondary importance should
10 be multi-species facilities that utilize
11 prohibited mammalian protein but do not
12 manufacture ruminant feed. As part of the
13 strategic approach we also recommend that FDA
14 and states enhance their coordination of
15 inspections and interpretation of inspection
16 results. In this regard, the recent
17 modification to FDA's BSE inspection checklist
18 are a positive step and should lead to improved
19 uniformity of inspection interpretations and
20 results.

21 FDA also asks what role, if
22 any, that public or private certification
23 programs should play. The NGFA strongly
24 supports government-based inspections by FDA and
25 states as providing the integrity and



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1 impartiality that's essential to maintaining
2 consumer confidence. The feed manufacturing
3 sector, the NGFA believes that the decision on
4 whether to participate in a public or private
5 certification program should be an individual
6 company decision based upon the perceived value
7 of such a certification vis-a-vis customer
8 preference and/or market demand.

9 The NGFA believes in the
10 integrity of our industry to truthfully attest
11 to their use or nonuse of prohibited mammalian
12 protein and has worked to facilitate marketplace
13 acceptance of individual company-to-company
14 assurances, including contractual guarantees,
15 company affidavits and other self-certification
16 mechanisms such as those that may be requested
17 by certain customers which are responsive to
18 customer needs. The NGFA's feed trade rules and
19 arbitration system as well as the courts provide
20 a time-honored mechanism for enforcing such
21 assurances.

22 Given the breadth and scope of
23 the feed manufacturing industry, the NGFA
24 believes that government actions to mandate or
25 endorse a private sector feed-based

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1 certification program are neither feasible nor
2 appropriate. While we do not oppose FDA
3 providing oversight of the integrity of private
4 sector feed-based certification programs if they
5 are requested to do so, we caution the agency to
6 secure the necessary assurances so that its role
7 is not misused to create winners or losers in
8 the marketplace. Simply put, we do not believe
9 a feed manufacturer's voluntary business
10 decision on whether or not to participate in
11 such a certification scheme should imply that
12 its feed products are any safer or less safe
13 than those who do not.

14 The FDA also asked about the
15 use of analytical tests capable of detecting
16 mammalian protein in ruminant feed. The NGFA
17 believes such tests should be employed by FDA as
18 an enforcement tool only if they have been
19 demonstrated to accurately, repeatedly
20 differentiate between prohibited and
21 non-prohibited mammalian material, including
22 blood, milk and gelatin products, without
23 resulting in false positives. Such tests also
24 should also be compatible with existing
25 FDA-approved equipment clean-out and sequencing



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1 procedures that have been the hallmark of the
2 medicated feed current for manufacturing
3 practice regulations.

4 To conclude our statement, I'll
5 now ask Mr. Gottula to present our thoughts on
6 operation-related questions posed by the FDA.

7 MR. GOTTULA: Thank you.

8 FDA asked several questions
9 concerning whether it should amend its BSE
10 prevention rule to require dedicated facilities
11 or transportation equipment.

12 The NGFA believes strongly that
13 the decision of whether to utilize dedicated
14 facilities to manufacture ruminant feed is a
15 decision that should be made by individual
16 companies based on the practicalities of doing
17 so, given the types of feed they manufacture and
18 customer preferences. In this regard the NGFA,
19 as part of its BSE prevention policy, has
20 recommended as a best management practice that
21 feed mills that manufacture ruminant feeds
22 voluntarily discontinue using prohibited
23 mammalian protein unless they have separate and
24 distinct mixing, handling and storage systems to
25 prevent accidental commingling or cross-



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1 contamination.

2 It is our understanding that
3 many feed manufacturers have made such a
4 business decision, either because they believed
5 it was the best way for them to comply with the
6 FDA rule or because of preferences from
7 customers or insurance carriers. But for some
8 feed manufacturers, using dedicated plants or
9 equipment may be impractical given the lines of
10 feed they manufacture. For this reason we
11 believe it would be inadvisable and costly for
12 FDA to mandate such a requirement.

13 The NGFA also does not believe
14 FDA should require dedicated transportation
15 equipment for hauling feed or feed ingredients
16 containing prohibited mammalian protein. Doing
17 so would increase delivery costs and disrupt
18 operating efficiency, which, in fact, has
19 occurred under just such a requirement imposed
20 in South Dakota.

21 The NGFA is taking proactive
22 steps to address transportation-related issues
23 associated with the FDA rule. Earlier this year
24 the NGFA established an animal protein
25 transportation task force, which I chair, that



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1 has drafted a set of best management practices
2 for transporting animal and plant protein in
3 compliance with the FDA rule. The task force
4 consists of representatives from the animal
5 feed, rendering, rail and truck and soy
6 processing industries. The draft best
7 management practices which are under review by
8 the task force identify procedures for using
9 dedicated transportation fleets,
10 customer-assigned equipment and clean procedures
11 if hauling both prohibited and nonprofit
12 mammalian material in the same conveyance. They
13 also cover loading and receiving procedures
14 applicable to the transportation providers,
15 plant and animal protein suppliers and the feed
16 manufacturers. Once finalized later this year,
17 we'll be disseminating these procedures widely
18 to companies within the relevant industries as
19 well as through FDA and states and encourage
20 that they be adopted.

21 FDA also posed two questions on
22 labeling. One asks whether the agency should
23 require labels to identify the specific
24 mammalian species from which the protein source
25 was derived and the other asks whether to amend



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1 the BSE caution statement to identify specific
2 ruminant species that are banned from being fed
3 products containing prohibited mammalian
4 protein.

5 The NGFA strongly opposes
6 changing either of these labeling requirements.
7 We believe that one of the strengths of the
8 current rule is that the labeling and caution
9 statements are well understood by feed
10 manufacturers and feeder customers. Changing
11 them could well create new confusion as well as
12 result in excessive costs for the feed
13 manufacturing industry as a result of the
14 labeling changes with little offsetting benefit.

15 Concerning the identification
16 of species-specific mammalian protein on labels
17 of all feed, the NGFA strongly supports use on
18 feed labels of the "animal protein products"
19 collective term as recognized by AAFCO.
20 Collective terms are extremely useful and
21 cost-effective for feed manufacturers because
22 they allow various ingredient sources that have
23 a similar function to be interchanged based upon
24 these cost formulations, without having to
25 change the list of individual ingredients that

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1 are preprinted on feed bags or tags.

2 The NGFA is unaware of any
3 misuse of the "animal protein product"
4 collective term that would justify a change to
5 species-specific ingredient labeling. In terms
6 of ensuring compliance with the BSE prevention
7 rule, it is the presence or absence of the
8 caution statement that feeders and feed
9 manufacturers look for to determine if the feed
10 is prohibited for ruminant species.

11 We also have not seen how such
12 a change would improve the efficiency of the
13 inspection process, as inspectors still would be
14 expected to review records to verify the source
15 of animal or plant proteins being used in feed.
16 If a customer requests such clarification, there
17 are other less costly methods, including written
18 and oral communication, to provide such
19 information.

20 We also believe that a
21 requirement to change the caution statement to
22 identify each type of ruminant is unnecessary
23 and, again, would impose labeling costs on feed
24 manufacturers and their customers. Commercial
25 feeding of sheep, goats, bison, elk and deer are

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1 relatively niche specialty markets whose feeders
2 fully understand they are feeding ruminant
3 animals.

4 The NGFA appreciates the
5 opportunity to provide its views on this
6 important matter and pledges its continued
7 efforts to achieve our mutual objective of
8 keeping the United States free of BSE.

9 Thank you.

10 DR. LUMPKIN: Thank you to both
11 of you.

12 Are there any questions of
13 either of these gentlemen?

14 (No response.)

15 DR. LUMPKIN: All right. Thank
16 you.

17 The next speaker is Mr. Ben
18 Jones, who is a board member of AAFCO, the
19 Association of American Feed Control Officials.
20 Mr. Jones is with the Texas Feed and Fertilizer
21 Control Service.

22 MR. JONES: Thank you,
23 Dr. Lumpkin.

24 I do currently serve on the
25 board of directors for the Association of

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1 American Feed Control Officials. On behalf of
2 AAFCO I wish to comment on the current rule, 21
3 Code of Federal Regulations Part 589.2000 to
4 help prevent the establishment and amplification
5 of BSE in the United States cattle herd.

6 AAFCO is an international
7 association with membership consisting largely
8 of state and federal feed control officials
9 responsible for administration of state laws,
10 rules and portions of the U.S. Food and Drug
11 cosmetic act pertaining to the distribution of
12 commercial feed and feed ingredients for
13 livestock, poultry and other animals, including
14 pets.

15 Currently all fifty states,
16 Puerto Rico, Canada, Costa Rica, United States
17 Department of Agriculture and the U.S. Food and
18 Drug Administration are members of AAFCO.

19 AAFCO recognizes that BSE is a
20 serious health threat to ruminant animals in
21 North America. BSE has had devastating effects
22 in Europe on animal and human health as well as
23 the livestock industries and economies of those
24 countries.

25 AAFCO is committed to achieving

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1 100 percent compliance with the federal rule
2 prohibiting the feeding of certain animal
3 protein products to cattle and other ruminants.

4 State members of our
5 association have conducted approximately eighty
6 percent of the inspections reported by the Food
7 and Drug Administration since the adoption of
8 the above regulations. AAFCO presents the
9 following responses, specifically to the
10 questions listed in the Federal Register:

11 One, what additional
12 enforcement activities, if any, regarding the
13 present rule are needed to provide adequate
14 public health control? We believe that to
15 improve compliance with the rule, more frequent
16 inspection and coordinated reinspection is
17 recommended for the feed manufacturing sector.
18 Inspection and compliance with the current rule
19 should be expanded to include all industries.
20 The agency must expand compliance inspections to
21 the livestock producer level. This could be
22 accomplished in the assistance and coordination
23 of the state animal health officials. Border
24 inspections need to be strengthened to prevent
25 the importation of feeds or feed ingredients not



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1 complying with the rule. Although it is
2 important to continue to educate, it is time to
3 start increasing enforcement activities. State
4 and federal application of enforcement
5 activities using the AAFCO enforcement
6 guidelines should be considered. Infraction
7 severity and associated regulatory action should
8 be evaluated and applied consistently.

9 2. Is the present rule
10 adequate to meet its intended objectives and are
11 there additional objectives that this rule
12 should now address? We believe that the current
13 rule is a labeling and recordkeeping regulation.
14 The agency should consider adopting good
15 manufacturing practices that could encompass all
16 of potential contaminants, including BSE agents,
17 for all animal feed and feed ingredients. The
18 rule should provide adequate guidance to all
19 involved parties and accommodate other potential
20 contaminants.

21 T. Should the present FDA ban
22 on the use of certain mammalian proteins in
23 ruminant feed be broadened? AAFCO feels this is
24 a science that -- requires a science-based
25 response. Some of the current exclusions

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1 deserve further scientific review. There is
2 still considerable debate concerning blood
3 products, plate wastes, tallow and poultry
4 litter.

5 4. Should FDA require
6 dedicated facilities for the production of
7 animal feed containing mammalian protein? The
8 intent and objectives of the rule are better
9 achieved when dedicated facilities or dedicated
10 mixing and conveyance equipment within the
11 facilities are used. When a facility making
12 ruminant feed does not handle prohibited
13 material, the chance of commingling,
14 contamination and accidental mixing or human
15 errors are minimized.

16 The above statement is based on
17 our facility inspection experience. The current
18 rule specifies that materials containing any
19 amount of prohibited mammalian protein must be
20 labeled with the cautionary statement. At this
21 time it is difficult to assure that current
22 flushing and sequencing procedures are adequate
23 to eliminate with 100 percent certainty any
24 amount of the BSE causative agents. We're not
25 aware that the agency has established an



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1 acceptable tolerance for prohibited protein in
2 ruminant feed. The potential for accidental
3 mixing warrants the consideration that ruminant
4 feeds and ingredients intended for ruminant
5 feeds be processed and assembled in a facility
6 or by equipment within a facility dedicated to
7 only handling nonprotein materials for ruminant
8 feed production. This requirement is viewed as
9 a positive step in preventing the occurrence and
10 amplification of BSE in the United States.

11 5. Should the FDA require
12 dedicated transportation of animal feed
13 containing mammalian protein? We believe that
14 requiring dedicated transportation of animal
15 feed containing prohibited mammalian protein is
16 viewed as another positive step in preventing
17 the occurrence and amplification of BSE in the
18 U.S. State feed regulatory agencies have very
19 limited authority over the transportation
20 system. The cleaning of transportation
21 equipment between delivery of various
22 commodities and feed ingredients appears to get
23 limited attention at this time.

24 Feed production facilities do
25 advise sequencing loads of animal feed when



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1 distributing within reason. In addition, the
2 manufacturers flush their distribution equipment
3 when sequencing is not possible. This could be
4 a prohibitive, resource-intensive activity to
5 observe and determine if distribution equipment
6 was actually being cleaned to eliminate any
7 amount of BSE causative agents. The agency
8 should consider the development of GMPs for the
9 transportation sector to provide regulatory
10 authority, not only for the BSE issue, but also
11 for all potential contaminants in animal feed.

12 At a minimum, the agency should
13 develop and mandate a validated clean method and
14 recordkeeping system for the transportation
15 industry to use. If feed manufacturers use
16 dedicated facilities to manufacture ruminant
17 feed, many of the trucks operated by the feed
18 manufacturers will essentially become dedicated.
19 However, trucks and rail cars used by the
20 commercial transportation industry that haul
21 many ingredients to the manufacturers may not be
22 dedicated. Transportation providers, their
23 equipment and employees may be difficult to
24 find, educate and regulate and will require a
25 coordinated effort with the federal Department



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1 of Transportation.

2 6. Should FDA require FDA
3 licensing of renderers and other facilities
4 engaged in the production of animal feed
5 containing mammalian proteins? If the intent of
6 a licensing requirement is to utilize the
7 license as an enforcement tool subject to
8 withdrawal of the license for violation of the
9 rule and this additional enforcement tool will
10 be used in a timely and appropriate manner, then
11 we feel this issue may have merit. Without
12 adequate regulatory tools and resources, the
13 agency may not be able to enforce this
14 provision.

15 However, we are not aware of
16 specific examples where this requirement would
17 provide assurance for the prevention and
18 amplification of BSE in the United States.
19 Amendment of the rule to require FDA licensing
20 of renderers and other facilities may not be
21 necessary since most, if not all, firms are
22 licensed by a state or federal agency.

23 Many, if not most, of the
24 states currently require licensing or
25 facility -- registration of facilities engaged



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1 in the production of animal feeds. Many states
2 also require licensing or permits for rendering
3 establishments. It would appear that with
4 continued cooperation between FDA and the states
5 that these facilities are identified. However,
6 if the FDA could identify renderers and feed
7 facilities that are not currently licensed and
8 inspected by a governmental agency with the BSE
9 rule for compliance, we would support FDA
10 licensing those firms.

11 7. Should FDA revoke or change
12 any of the current exclusions for certain
13 products allowed in the current rule? This
14 question requires a science-based response. As
15 previously mentioned, blood products, plate
16 wastes, tallow and poultry litter deserve
17 further scientific review.

18 8. Should FDA add to the list
19 of prohibited material in ruminant feed, that
20 being the term poultry litter and other recycled
21 poultry waste products? Again, this question
22 requires a science-based response. The concerns
23 we have of poultry litter is not only the
24 prohibited protein that goes through the
25 digestive tract of the bird, but also the

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1 unconsumed feed containing prohibited protein
2 that is found in the latter through feed
3 spillage.

4 9. Should FDA remove the
5 exemption for pet foods from labeling with the
6 precautionary statement? The exemption of the
7 caution statement on pet food products can and
8 does lead to confusion and misunderstanding in
9 certain segments of the feed and feeding
10 industry. This statement is made based on
11 several concerns. The first concern was in
12 regard to the use of salvaged pet food products.
13 Broken bag product is being picked up from
14 establishments handling pet products. This
15 product is being further processed and may be
16 used in other animal diets. Although much of
17 this product is making its way into swine feed,
18 on occasion there is some concern that product
19 is being converted for distribution to ruminant
20 animals.

21 The second concern is in regard
22 to the storage of packaged dry pet food at feed
23 manufacturing establishments and on-farm.
24 Animal producers, employees of the feed
25 manufacturing establishments and purchasers of



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1 animal feed have been educated to recognize
2 protein material on the basis of the labeled
3 caution statement. Since packaged pet food is
4 not required to contain the caution statement
5 established in the rule, there is concern that
6 material from broken bags, leftover materials,
7 or even intact pet food containers are not being
8 recognized as prohibited material and could be
9 incorporated into ruminant feed. In addition,
10 pet food may be a source of imported animal
11 proteins.

12 Preferably the agency should
13 reconsider the current exemption for pet food to
14 be labeled with the caution statement.

15 10. Should FDA extend its
16 present recordkeeping requirements beyond one
17 year? At the current time, the one-year
18 recordkeeping requirement appears to be adequate
19 to do trace-forward and trace-back inspections.
20 However, should there be a reported case of BSE
21 in the United States, the one-year recordkeeping
22 requirement may be inadequate to determine the
23 source of the causative agent.

24 11. Should FDA change its rule
25 to require labeling of protein-containing feed

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1 to specify what types of mammal was used in the
2 production of the protein? We believe yes,
3 requiring the listing of the type of mammal,
4 along with the specific ingredient, would be of
5 value in preventing the occurrence and
6 amplification of BSE in the United States. This
7 requirement would assist the purchaser to know
8 clearly what ingredients and sources are
9 contained in a feed ingredient or mixed feed
10 product. The current use of the collective
11 "animal protein products" also creates unclear
12 situations and inadequate label information for
13 the purchaser.

14 12. Should the required
15 cautionary statement be changed to read "Do not
16 feed to cattle, sheep, goats, bison, elk or
17 deer?" We believe it should not read as such,
18 but feel that in order to make the statement
19 more clear and still be comprehensive, we
20 suggest changing the cautionary statement to
21 read, "Do not feed to cattle, sheep, goats, deer
22 or other ruminants." This statement would list
23 the common ruminants and would still leave it
24 open to include other ruminants as well.

25 13. What new information is

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1 available on potential efficient, accurate
2 analytical methods that may be used in detecting
3 mammalian proteins, and what should the sampling
4 parameters of such a program be? AAFCO has no
5 comment at this time. We think that is a
6 question that will need to be addressed by the
7 scientific community and experts that are
8 currently working in this area.

9 14. Regarding enforcing
10 compliance with the rule, what further
11 authorities, if any, would be desirable in order
12 to enforce the rule adequately? We believe that
13 in general the states have adequate authorities
14 available to enforce the rule. It appears that
15 the agency could use additional enforcement
16 authority and tools. We suggest that the agency
17 may be interested in reviewing the AAFCO
18 enforcement guidelines and craft their
19 enforcement authorities to parallel those
20 stated. Civil penalties and withdrawals from
21 distribution should be considered for adoption
22 at the federal level.

23 15. Regarding helping to
24 increase compliance with the rule, what role, if
25 any, should public or private certification



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1 programs play? AAFCO believes that public
2 agencies and private entities should continue to
3 be a leader in providing education pertaining to
4 the requirements of the rule to their members
5 and the public. We do not believe that public
6 or private certification programs should be
7 utilized to judge compliance of a firm.
8 Adequate state and federal resources are
9 available to make a determination of a firm's
10 compliance with the rule.

11 State and federal inspection
12 conclusions should be shared with inspected
13 establishments to demonstrate that the
14 establishment is operating within or outside of
15 compliance with the rule. This will enable the
16 industry the ability to provide the necessary
17 assurances to their customers. Compliance with
18 the rule is mandatory and should not be a
19 component of a marketing program.

20 16. Regarding the import of
21 feed, what should the restrictions on such
22 import be? The restrictions should be country
23 specific and a determination should be made that
24 the country has in place restrictions that are
25 equal to or greater than those in the United



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1 States.

2 And finally, are there any
3 other additional measures that are necessary to
4 guard against BSE and new variant CJD in the
5 United States? We bode the question that if all
6 state and federal feed regulatory agencies
7 achieved 100 percent compliance from all sectors
8 of the animal feed industry and allied
9 industries and other involved federal agencies
10 achieved their objectives to prevent BSE from
11 occurring in the U.S., would this prevent the
12 likelihood of an occurrence of BSE in this
13 country? We know that TSEs are naturally
14 occurring diseases in many animal species and
15 are occurring in some populations, including our
16 own. We must attempt to minimize the potential
17 impact of an occurrence of BSE. The intent of
18 the current BSE rule is to prevent the spread
19 and amplification of the disease. The FDA must
20 attempt to minimize the potential impact of an
21 occurrence of BSE on the agricultural community
22 and consuming public.

23 The agency and states must have
24 an enforcement rule and provide adequate
25 resources to enforce it. Reaction to mishaps



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1 that have already occurred must be dealt with;
2 however, proactive approaches must be reviewed
3 and then implemented. Enforcement tools must be
4 in place and used at the federal level that are
5 of significant consequences to the parties
6 involved which are not in compliance with the
7 rule.

8 The agency should encourage and
9 support all state feed control officials to
10 incorporate a BSE inspection component into
11 their routine feed inspection programs. The
12 results of those state inspections should be
13 shared with FDA to be entered into a national
14 database tracking compliance with the BSE rule.

15 On behalf of the Association of
16 American Feed Control Officials, I would thank
17 the Food and Drug Administration for the
18 opportunity to provide these comments.

19 DR. LUMPKIN: Thank you,
20 Mr. Jones.

21 Any questions?

22 (No response.)

23 DR. LUMPKIN: Thanks again.

24 Our next speaker is Randall
25 Gordon. Mr. Gordon is the vice president of



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1 communications and government relations for the
2 National Grain and Feed Association. My
3 understanding is that he's been authorized by
4 the Pet Food Institute to speak on their behalf
5 at this time, and he will be doing that and not
6 speaking on behalf of the NGFA.

7 MR. GORDON: Thank you, Dr.
8 Lumpkin.

9 I am speaking today on behalf
10 of the Pet Food Institute, the trade association
11 that represents the manufacturers of 95 percent
12 of the dog and cat food sold in the United
13 States.

14 The Pet Food Institute was
15 unable to have a representative here today
16 because it is conducting its annual board of
17 directors and annual industry meeting in
18 Chicago.

19 The National Grain and Feed
20 Association and Pet Food Institute have
21 developed a strategic alliance to work together
22 on issues of mutual interest between our
23 different industries. It is under that
24 arrangement that I offer the following comments
25 on behalf of the Pet Food Institute in response

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1 to the agency's questions that are under
2 consideration here today.

3 The Pet Food Institute and pet
4 food industry has and continues to support the
5 government's efforts to prevent the introduction
6 of BSE into the United States and the safeguards
7 that are currently in place. We agree that the
8 need for a cautionary statement on pet food sold
9 at retail has already been addressed by the
10 agency in its 1997 rule-making and does not need
11 to be considered again.

12 In January 1997, the FDA
13 proposed a cautionary label on pet food sold at
14 the retail level as part of its efforts to
15 prevent the amplification of the BSE
16 disease-causing agent, should it ever be found
17 in the United States. FDA, in its final Federal
18 Register notice later that year, agreed that a
19 label on pet food sold at retail was not needed.
20 The agency noted, quote, "FDA agrees that the
21 cautionary statement serves no useful purpose on
22 pet food. .These products typically cost
23 substantially more per ton than most complete
24 feeds intended for food-producing animals.
25 Therefore, there is little, if any, risk that



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1 pet foods...will be purchased at full price for
2 use in ruminant rations," unquote.

3 As was the case in 1997, under
4 a cautionary labeling scheme, pet foods would be
5 the only retail products to carry a
6 precautionary statement on the label. As the
7 research conducted by the Pet Food Institute
8 previously presented to the FDA indicated, such
9 a label would not only have a negative effect on
10 pet food by unnecessarily alarming consumers, it
11 would also have a negative impact on human
12 foods. PFI's research has found that 71 percent
13 of consumers would buy something else if they
14 saw such a label on pet food; 68 percent would
15 be very concerned about the safety of the pet
16 food if it carried such a label; and 40 percent
17 of the respondents would be very concerned about
18 consuming beef and lamb because of the label on
19 pet food products sold at retail.

20 Since, as the agency correctly
21 points out, dog and cat food sold at retail is
22 neither designed nor priced to serve as ruminant
23 feed, the necessity for such a label at the
24 retail level is further decreased. Salvage and
25 distressed pet food, as is currently required,



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1 should continue to carry the label "Do not feed
2 to cattle or other ruminants," and the industry
3 recognizes its responsibility to ensure such
4 materials are handled in compliance with the
5 regulation when used in animal feed.

6 The Pet Food Institute has
7 taken a number of steps to remind its members,
8 other organizations and state government
9 officials of the importance of complying with
10 the salvage and distressed pet food labeling
11 requirements and will continue its efforts to
12 prevent these products from being included in
13 ruminant feed. PFI believes the proper
14 enforcement of the current labeling regulation
15 is the best method to prevent the inclusion of
16 salvage and distressed pet food in ruminant
17 feed.

18 In conclusion, the Pet Food
19 Institute, on behalf of its member companies,
20 believes the agency was correct in 1997 that a
21 cautionary statement on retail pet food products
22 was not necessary. The efforts to prevent BSE
23 from entering the United States have been
24 successful since 1997 in the rule that was
25 issued. A cautionary statement on pet food



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1 products is not warranted and the current
2 regulation should not be amended.

3 Thank you.

4 DR. LUMPKIN: Thank you.

5 Are there questions?

6 DR. SUNDLOF: Yes.

7 DR. LUMPKIN: Steven.

8 DR. SUNDLOF: Randy, it says
9 here in the PFI statement, numbered steps. Is
10 there official guidance out for that?

11 MR. GORDON: Steve, I am going
12 to have PFI respond to this in writing, if you
13 don't mind. They have had some communication
14 with some of the dairy industry and some of the
15 state directors of agriculture on this issue,
16 and I think I can ask them to make that
17 available and respond to that question.

18 DR. SUNDLOFF: The other thing,
19 the research is that a 71 percent of consumers
20 would buy something else if that was on the
21 label. What's "something else"?

22 MR. GORDON: Again, if I could,
23 I'll ask them to respond in writing to that.

24 DR. LUMPKIN: Thank you again.

25 Our next speaker is Brad



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1 Gottula, director of quality assurance, Land O'
2 Lakes Farmland Feed in Fort Dodge, Iowa. He
3 will be speaking on his own behalf at this
4 point.

5 MR. GOTTULA: Thank you.

6 As was mentioned, I'm the
7 director of quality assurance and regulatory
8 affairs for Land O' Lakes Farmland Feed. Our
9 company operates 95 feed manufacturing plants in
10 29 states in the U.S. and in the province of
11 Ontario, Canada. In addition, our grain and
12 feed products are manufactured at over 200
13 locally owned cooperatives in North America.
14 Our company supports the efforts by the FDA and
15 other governmental agencies to prevent BSE from
16 ever becoming a threat in this country. We
17 appreciate the opportunity to respond and give
18 our insight to several of the thought-provoking
19 questions that are the focus of this important
20 hearing.

21 In regards to Question 1, what
22 additional enforcement activities, if any, are
23 needed regarding the present rule to improve
24 public health controls and what suggestions
25 would those be? We do not believe additional



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1 enforcement tools or measures are needed to
2 enforce 21 CFR 589.2000 that ultimately would
3 provide improved safety and public health. The
4 overall educational efforts that have been
5 ongoing for the last four years need to remain a
6 primary focus in order to make sure all feed
7 manufacturers and animal producers are
8 adequately informed and educated about this
9 important rule.

10 One of the biggest areas of
11 confusion or inadequacy that is existent with
12 this rule is that some feeders, small feed
13 dealerships and non-FDA licensed feed
14 manufacturers to not seem to understand all the
15 rule requirements and exemptions. This
16 ultimately leads to noncompliance issues and
17 misinformation as well as confusion in the
18 marketplace. Continued efforts to educate all
19 entities that are the subject of this rule must
20 be undertaken to improve understanding and
21 compliance. An approach of using targeted
22 inspections of firms who have not consistently
23 proven to be adequately informed and in
24 compliance or of those firms who are actually
25 rendering or using prohibited mammalian proteins



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1 may be an effective method to improve compliance
2 with the requirements of this rule.

3 In regards to Question 3,
4 Should the present FDA ban on the use of certain
5 mammalian proteins in ruminant feed be
6 broadened? The present rule that bans the use
7 of certain mammalian proteins in ruminant feed
8 should only be broadened if compelling
9 scientific evidence supports the fact that an
10 ingredient or product may be a carrier of the
11 BSE agent. Banning products based on anything
12 other than scientific evidence leaves the feed
13 industry and our customers prey to the emotion
14 and speculation that ultimately damages the
15 credibility of our nation's animal feed and food
16 supply. Suggestions to ban approved feed
17 ingredients such as blood products, gelatin and
18 milk products should be halted as scientific
19 evidence from extensive studies done in Europe
20 in the past by the World Health Organization as
21 recently as mid to late '90s have proven that
22 blood products do not carry the BSE agent. Any
23 revocation of an exemption or excluded product
24 currently allowed under 21 CFR 589.2000 should
25 and must be based on sound science. If

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1 compelling scientific evidence does not prove a
2 product is a carrier of the BSE agent, it should
3 be allowed or continued to be allowed as an
4 approved feed ingredient for specific species of
5 animals.

6 Question 4, Should the FDA
7 require dedicated facilities for the production
8 of animal feed containing mammalian protein to
9 decrease as much as possible the possibility of
10 commingling during production? Many feed
11 companies, including Land O' Lakes, Farmland and
12 Purina Mills have voluntarily made this decision
13 either soon after the publication of the rule in
14 1997 or more recently. The voluntary stance
15 many companies have adopted and Land O' Lakes
16 Farmland Feed supports regarding not
17 manufacturing ruminant feeds in facilities that
18 utilize prohibited mammalian proteins or to
19 simply not utilize prohibited mammalian proteins
20 in their feed mills is working, and there is
21 little added benefit foreseen in making this a
22 mandatory requirement with the absence of BSE in
23 this country.

24 Regarding Question 5, Should
25 FDA require dedicated transportation of animal

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1 feed containing mammalian protein to decrease as
2 much as possible the possibility of commingling?
3 From an efficiency standpoint, this will
4 increase delivery costs and the operational
5 challenges to effectively transport feed and
6 feed ingredients.

7 The recent enactment in South
8 Dakota of specific transportation and handling
9 regulations for delivery vehicles transporting
10 ruminant feeds and feeds that may contain
11 mammalian proteins will increase the costs for
12 feed manufacturers, dealers and customers
13 because it is removing transportation
14 efficiencies that feed manufacturers have
15 utilized in a safe and efficient manner for many
16 years.

17 Today in South Dakota two
18 delivery vehicles may now be required to deliver
19 a feed shipment depending on the type of feed
20 that, in the past, was usually taken care of by
21 one vehicle. At \$1.40 per gallon for fuel for
22 delivery vehicles that typically average six to
23 seven miles per gallon, this is very expensive
24 for feed manufacturers and haulers, and these
25 costs will be passed on to customers.

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1 In the case of prohibited
2 mammalian protein ingredients that are delivered
3 to feed manufacturing sites, we believe there
4 may be some inherent benefit in having dedicated
5 trailers and rail cars for these products, as
6 this will likely reduce cross-contamination
7 issues. However, additional costs will be
8 incurred and likely passed on to manufacturers,
9 dealers and customers.

10 Regards to Question 11, Should
11 FDA change its rule requiring labeling of
12 protein-containing feed to specify what types of
13 mammal was used in the production of the
14 protein? AAFCO has utilized and the FDA has
15 endorsed the use of the collective feed term
16 concept in 35 states since the early 1970s. The
17 concept is based on the sound nutritional
18 principle that animals do not require any
19 specific feed ingredient but need nutrients that
20 can be provided by a wide range of ingredients.
21 The benefits of these terms are many, but
22 primarily result in lower cost to the
23 producer/customer without any sacrifice in
24 safety or nutrition. No other labeling concept
25 has been nearly so successful in the feed



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1 industry.

2 Of the seven collective terms
3 acting legally as definitions on feed labels,
4 the one with the most concern is "animal protein
5 products." In 1998 AAFCO asterisked all the
6 feed definitions within this term which are
7 prohibited/restricted in ruminant feeds as per
8 21 CFR 289.2000. The feed industry strongly
9 supported this effort.

10 FDA requires firms to place the
11 caution statement, "Do not feed to cattle or
12 other ruminants" on any label or label
13 containing or likely to contain any substances
14 prohibited in ruminant feed. This statement is
15 the sole indicator that if feed is likely to
16 contain a restricted-use protein product from
17 the list of asterisked products in the AAFCO and
18 protein product collective term. If a firm does
19 not use the cautionary statement, it indicates
20 that the feed does not contain restricted food
21 products.

22 Some regulatory officials
23 believe that doing away with the "animal protein
24 products" collective term would simplify
25 regulatory obligations. This view is not

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1 necessarily correct, as verification of the
2 ingredients actually used in a feed formula
3 requires review of formula records, regardless
4 of whether a collective term is used. For
5 example, if a firm were to use the term "meat
6 and bone meal" only on a label without the
7 collective term, verification would still be
8 required in order to document the actual
9 ingredient used is indeed the one on the label.

10 If AAFCO or FDA were to change
11 the protein ingredient names to require species
12 names, as is already voluntarily allowed, the
13 names can be porcine or pork meat and bone meal
14 and bovine or beef meat and bone meal. If a
15 firm chooses to use one of these names on a
16 label with or without the cautionary statement,
17 investigators would still be required to examine
18 formulas and ingredient records to verify if, in
19 fact, the correct product and ingredient name
20 were used. Any changes made to collective term
21 or ingredient listings on feed labels must be
22 based on a sound understanding that the changes
23 will result in better compliance, better
24 regulation or better prevention of BSE.
25 Moreover, a review of the inspection data

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1 collected by FDA should clearly reveal that
2 either there is widespread abuse of the term or
3 serious misbranding to justify changing these
4 ingredient names. That justification does not
5 exist at this time.

6 Regulatory changes regarding
7 use of collective feed labeling terms will
8 result in substantial costs to change feed
9 labels, and feed manufacturers and regulatory
10 agencies must justify the costs for any benefits
11 derived. Regulatory changes regarding changes
12 in accepted feed labeling practices moves our
13 industry further from having uniform feed
14 labeling guidelines across state lines and
15 further hampers effective and efficient business
16 practices, as mentioned earlier with the example
17 in South Dakota and the additional regulations
18 they have not implemented regarding feed
19 labeling, handling and transportation. As the
20 U.S. does not have BSE, it is difficult to
21 justify this major change to feed labeling
22 regulations.

23 In regards to Question 12, In
24 order to make the statement clearer, should the
25 required cautionary statement on the label of

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1 products that contain protein derived from
2 mammalian tissues and that are intended for use
3 in animal feed be changed to read, "Do not feed
4 to cattle, sheep, goats, bison, elk or deer."?
5 We do not believe changes are needed in the
6 caution statement, as the statement is adequate
7 to communicate the intended information,
8 provided people using the product look for the
9 statement and read and follow the product
10 label. A change in the caution statement
11 wording would be quite costly to the feed
12 industry, and would provide little, if any,
13 added benefit to the feed customer and consumer
14 who ultimately must pay for these changes.

15 In regards to Question 15,
16 regarding helping to increase compliance with
17 the rule, What role, if any, should public or
18 private certification programs play?
19 Certification programs can exist in a variety of
20 forms. Affidavits and self-certification forms
21 are and should be widely accepted, as many
22 companies are in compliance with this rule and
23 have excellent documentation, and their quality
24 assurance and regulatory programs that prove
25 this. FDA has recently updated their BSE



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1 inspection form to include an inspection finding
2 summary section in which, when the inspection
3 finding or inspection report is eventually
4 shared with the firm that's been inspected,
5 compliance or noncompliance with the BSE rule is
6 documented. This should be ample proof to any
7 feed customer or livestock buyer that the firm
8 in question is in compliance with 21 CFR
9 589.2000. Fee-based third-party certification
10 programs may be of interest to some companies,
11 but our view is that FDA must be cautious in
12 whether or not it endorses such certification
13 programs as this may open the door to unfair
14 competition in the marketplace by companies who
15 would possibly leverage livestock buyers and
16 food companies to only purchase animals fed by
17 third-party certified feed manufacturers. Our
18 firm belief is that state and federal BSE
19 inspection programs are working and should
20 continue to be the compliance indicator for the
21 regulated industry. Funding should continue to
22 be directed toward this end.

23 Land O' Lakes Farmland Feed
24 appreciates the opportunity to share our views
25 on this important feed regulation. We have

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1 worked diligently to inform our employees and
2 customers of this rule's requirements and pledge
3 to continue to do all we can to prevent BSE from
4 threatening our nation's feed and food supply.
5 We would like to commend the FDA for its
6 scientific view of this important issue and urge
7 that they continue to foster open dialogue and
8 reason regarding this rule as it is evaluated as
9 to its effectiveness.

10 DR. LUMPKIN: Thank you.

11 Mr. Gottula. Any other questions?

12 (No response.)

13 DR. LUMPKIN: Thank you, sir.

14 I'd like to ask now Mr. Mark
15 Hohnbaum to come to the podium. Mr. Hohnbaum is
16 with H.J. Baker & Brother, Inc., in Little Rock,
17 Arkansas.

18 MR. HOHNBAUM: My name is Mark
19 Hohnbaum, and I am the representative of H.J.
20 Baker & Brother, Inc. H.J. Baker & Brother has
21 served the feed food industries for 151 years.
22 One of our largest businesses is animal and
23 marine protein formulate. We have four domestic
24 plants for this application.

25 As one of the largest consumers

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1 of rendered animal proteins in the United
2 States, we have a unique perspective on the
3 rendering industry. We purchase material that
4 runs the gamut from fish to fowl and beef to
5 pork. Our suppliers range in scale from the
6 fully integrated multi-nationals to the mid-size
7 independent renderers and finally down to the
8 tiny one-plant operators.

9 From this view some things are
10 apparent that may not be obvious from the
11 outside looking in.

12 Education about what our
13 industry really is started more than thirty
14 years ago with an isolated few. It has
15 accelerated through the past five years to a
16 point where all rendering industry employees now
17 know we are in the food business. This
18 understanding lends a certain gravity to all
19 activities undertaken.

20 In the late 1980s, when the
21 first reports of a causal link between meat and
22 bone meal from scrapie-infected sheep being fed
23 to cattle was postulated as the source of BSE,
24 our company, with the majority of U.S. rendering
25 and feed industry companies, voluntarily removed

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1 this risk material from our plants. We see
2 amazing variety in this industry. But we see
3 total unanimity in the knowledge that total
4 compliance and complete adherence to feed ban
5 rule is vital to public health and our
6 industry's future.

7 This is a responsive and
8 responsible industry manned by smart people. We
9 not only see the fruits of our labor but sit
10 down at mealtime with our families and consume
11 its ultimate products. We value food safety.

12 We also value valid science.
13 The best science today suggests that TSEs are a
14 complex and vexing category of diseases.
15 However, working from today's generally accepted
16 postulates, the transmission agent is prion.
17 This prion from the sheep with scrapie infected
18 cattle in the U.S. and started the BSE epidemic
19 that they are fighting today. Many factors that
20 were present in the U.K. beef food industry in
21 the early 1980s have been and are dramatically
22 different here in the U.S. High versus low
23 sheep/cattle ratio, low versus high temperature
24 rendering systems, high versus low cattle herd
25 age, and high versus low -- now no --

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1 ruminant-derived protein in ruminant feed
2 rations. These obvious differences could go a
3 long way toward explaining why the disease
4 didn't spontaneously generate here.

5 When coupled with the USDA's
6 ban on imported cattle from suspect countries
7 and subsequent bans on meat and bone meal from
8 these same countries, then our risk at that time
9 was very, very low. Add to these factors
10 FDA-CVM's well conceived and comprehensive rule
11 based on the best science available, coupled
12 with strict enforcement, and it has reduced the
13 risk to the limits of detectability.

14 Safeguards are in place and
15 working. FDA-CVM's mandate to protect
16 human/animal health has been well served by this
17 regulation. Reopening the rule would increase
18 public anxiety, not public safety. Let the
19 regulation stand. Do not reopen the rule.

20 Thank you very much.

21 DR. LUMPKIN: Thank you, sir.

22 Any questions.

23 (No response.)

24 DR. LUMPKIN: Thank you again.

25 I'd like to now call on

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1 Mr. Michael Malecha, who is president of AG
2 Innovations in Madison, Wisconsin.

3 MR. MALECHA: Thank you,
4 Dr. Lumpkin. I'm Mike Malecha, and I am
5 president of AG Innovations in Madison,
6 Wisconsin.

7 As consultants to the food,
8 feed and industrial agricultural industry, our
9 main focus is to work with client companies to
10 effectively manage their co-products to greater
11 value, both economically and environmentally.
12 Maintaining feed and food safety is paramount in
13 the fulfillment of our responsibilities.

14 As an active member of the feed
15 industry, I currently serve on the board of
16 directors, chair the feed trade rule
17 subcommittee and serve on the feed and industry
18 committee of the National Grain and Feed
19 Association. I recently served as a member of
20 the liquid feed committee of the AFIA. During
21 my 26 years in the food and feed industry, I
22 most recently spent eleven years at Kraft foods
23 North America as manager of by-products and feed
24 ingredients, and prior to that for nearly ten
25 years at Ralston Purina Company managing feed

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1 ingredient purchasing in their pet food and
2 grain divisions.

3 To start out, it's important to
4 reiterate: There's not been a single case of
5 BSE found in the United States today. Due to
6 active surveillance by the FDA and USDA and
7 strong industry support by feed manufacturers,
8 livestock producers, meat processors,
9 transportation industry, food manufacturers and
10 purveyors, veterinarians and trade groups, the
11 science-based regulations currently in force
12 have facilitated the goal of keeping BSE from
13 entering our country. The FDA should be
14 commended for their leadership in preventing
15 BSE, and for being the linchpin in the
16 protection of our food and feed supply. The
17 establishment and enforcement of the three
18 firewalls has provided a sound strategy in that
19 effort.

20 We strongly believe that the
21 FDA must continue to base its position on sound
22 science as we move forward. As new scientific
23 information is confirmed, the strategy should be
24 adjusted to accommodate it. It is vitally
25 important that FDA maintains its high standards

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1 and its reputation as the lead agency in food
2 safety in the United States and in the entire
3 world. Because of that leadership and the
4 support of the entire food industry, the public
5 will continue to enjoy the safest food supply
6 available. To continue in those efforts I
7 recommend that the FDA should maintain the
8 program of direct inspection by providing the
9 necessary resources and enlisting the support of
10 the state feed control agencies to inspect meat
11 facilities and transportation concerns. The
12 regulatory task can be accomplished. It is our
13 view that affidavits of compliance and bona fide
14 third-party inspections as APPI has undertaken
15 are effective measures as long as there's
16 definite periodic inspection by the FDA or their
17 state counterparts. To endorse or recommend
18 certification by not-so-independent arms or
19 organizations as a means to reduce FDA
20 inspections would undermine the confidence and
21 support of the food industry and the public at
22 large and would damage the reputation of the FDA
23 that it currently enjoys. These latter
24 certifications, while certainly providing
25 augmentation to company best practices, are

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1 viewed by much of the food industry as not
2 independent enough and as possibly
3 anti-competitive due to their nature when foods
4 produced from these products may be certified as
5 beneficial and superior. We stand behind the
6 FDA and the BSE prevention effort. A strong
7 science-based FDA adds credibility to the food
8 and feed industry in the global economy as well.

9 To improve compliance with the
10 rule we'd recommend that the FDA and state
11 agencies forge a strong inspection and
12 compliance program that is driven by a tracking
13 system from the initial source to an ultimate
14 user. By using a trace-forward approach, a
15 targeted inspection program can be implemented
16 in an effective and efficient manner to best
17 deliver the necessary feed safety. It is
18 vitally important that adequate funding be
19 provided by congress to carry out the strategies
20 to meet full compliance with the rule.

21 Regarding the present rule and
22 its objective, we believe the current rule is
23 satisfactory as written.

24 The issue of dedicated
25 facilities should be left to the individual



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1 companies to decide based on their ability to
2 manage the process. As a recommended best
3 practice, separate facilities or fully separate
4 systems would be preferred; but the ultimate
5 decision should left to the individual business.
6 To require separate facilities would be
7 anti-competitive and could be financially
8 detrimental to some concerns.

9 The transportation method
10 should be left up to the shipper and receiver to
11 decide, provided best management practices are
12 employed to comply with the rule. To restrict
13 shipment to dedicated conveyances would be
14 extremely costly and lead to unnecessary
15 overcapacity and/or significant delays in
16 service.

17 We do not believe that the FDA
18 should change or revoke any of the exclusions to
19 the current rule, nor should the agency add to
20 the list of prohibited materials unless there is
21 compelling science-based evidence to do so.
22 Unless new scientific evidence is available, the
23 feeding of plate waste, which includes
24 previously USDA-inspected cooked meats, should
25 continue. Reverting that product to landfill or



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1 other destruction would add to groundwater
2 issues or things that are governed by EPA and
3 increase cost to the restaurant and food
4 industry.

5 Unless science supports the
6 addition of dairy or gelatin to the prohibited
7 list, we do not support that for convenience, as
8 it would send a negative message to consumers
9 who regularly purchase those foods for their own
10 use.

11 We would recommend that FDA
12 continue to exempt pet foods from labeling in
13 the precautionary statement. Salvage pet food
14 should be properly noted with a precautionary
15 statement on the shipping documents, however.
16 Present use of mammalian feeds where packaging
17 is destroyed in the process, and having it on
18 the label would add no value.

19 I want to thank the FDA today
20 for scheduling this hearing and for the
21 opportunity to provide these remarks.

22 DR. LUMPKIN: Thank you very
23 much.

24 Are there any questions of
25 Mr. Malecha?

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1 I have one question, and
2 perhaps it's a bit rhetorical. I thought it was
3 interesting, you made the point that you had a
4 concern that if certain products were now said
5 to be unable to be used in animal feed, that
6 that might have a negative effect on consumers
7 because they would misinterpret this.

8 MR. MALECHA: Yes, sir.

9 DR. LUMPKIN: Is there any
10 other evidence that that happened when the
11 original ban went into effect and we said you
12 can't feed beef to cattle? Did that have a
13 negative effect on the consumers' view that beef
14 was safe in this country?

15 MR. MALECHA: I'm not sure we
16 saw a measured response to that very
17 specifically. What happened in the biotech area
18 in relation to -- well, not only organic but any
19 biotech concerns in products and the
20 relationship is pretty close, especially as
21 we've seen in the press and everything else.
22 Bringing other diseases and linking them with
23 BSE, we see that that potential does exist.

24 Also it's subject, obviously,
25 to mismarketing, and you're never totally safe

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1 in that process.

2 DR. LUMPKIN: Fair enough.

3 Thank you, sir.

4 Our last speaker before the
5 afternoon break is Steven Roach with the Food
6 Animal Concerns Trust out of Chicago, Illinois.

7 MR. ROACH: Yes. I would like
8 to thank the FDA for providing us the
9 opportunity to present these comments.

10 Food Animal Concerns Trust is a
11 nonprofit organization that advocates better
12 farming practices to improve the safety of meat,
13 milk and eggs. FACT was at the table when the
14 federal strategy to keep U.S. cattle free from
15 bovine spongiform encephalopathy, BSE, was
16 fashioned several years ago, and FACT worked on
17 the drafting of the FDA rule to prohibit certain
18 types of mammalian protein from ruminant feed,
19 which we are reexamining today. FACT's position
20 on BSE is based on an awareness of the real
21 risks of transmissible spongiform
22 encephalopathies, TSEs, to human and animal
23 health, combined with an acute sensitivity to
24 the current scientific uncertainties on how this
25 class of diseases is transmitted both within and

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1 between species.

2 FDA has requested public
3 comments on several aspects of the existing role
4 to limit the spread of BSE through the
5 regulation of animal feed. FACT commends the
6 FDA for the work they have done so far in
7 creating the original role and enforcing its
8 provisions, but we feel that the time is right
9 for a re-evaluation of the regulation.

10 Since 1997 we have seen the
11 disease spread throughout Europe, and it has now
12 been found in Asia. The profile of the disease
13 in Europe indicates how easily the disease can
14 spread when controls on feeding are not
15 stringently enforced. So the evidence in Europe
16 is that they did have effective rules and
17 regulations, but that enforcement of the
18 regulations failed, and that's why they've been
19 getting more new cases. So what it looked like
20 in Europe happened was we had the disease got to
21 a country, and then the people started enforcing
22 the regulations, and we fear there's a risk of
23 that scenario happening here as well. The
24 unexpected appearance of BSE in Japan suggests
25 that other countries outside of Europe may have



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1 undetected cases, and there is a real risk that
2 feedstuffs containing the disease or the
3 affected material will be imported into the U.S.
4 It is important to note that we did not have
5 restrictions on importing feed from Japan during
6 the period when the disease was present but
7 undetected. And I wasn't able to get the exact
8 figures on it, but I think in the last year we
9 imported 10,000 metric tons of feed from Japan.
10 So's not a lot of feed, but it is some. And
11 it's not clear how much of that might have had
12 meat and bone meal in it.

13 Because BSE is currently
14 developing into a worldwide problem, spreading
15 from its appearance in a single nation, the
16 United Kingdom, FACT calls on the FDA to broaden
17 the scope of the FDA ban and to more rigorously
18 enforce the current provisions.

19 I will now discuss the
20 questions on which the FDA has requested
21 comments.

22 For Question No. 1, FDA needs
23 to respond quickly to operations that are out of
24 compliance with the rule. In a recent report
25 provided by the FDA's Center for Veterinary



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1 Medicine, CVM, over 500 businesses were found to
2 be out of compliance. Almost 400 of these firms
3 that were out of compliance handled both
4 ruminant and nonruminant feed. Perhaps even
5 more disturbing is the fact ten firms that
6 handle both ruminant and non-ruminant feeds met
7 none of the requirements of the rule and have
8 not been reinspected since the end of 1998. We
9 accept that the compliance inspection process is
10 an arduous task, but here we have a clear case
11 of rule violations with no follow-up in over two
12 years. According to the rule, these businesses
13 are clearly in violation of the Act and are
14 marketing the illegally adulterated animal feed.
15 If after a prompt follow-up inspection the
16 business is still not in compliance with the
17 law, the FDA should use its authority to
18 confiscate and condemn any illegally adulterated
19 feed. This would obviously include any feed
20 intended for sale as ruminant feed by the
21 out-of-compliance entity.

22 Okay. For Question No. 2.

23 FACT believes that the current rule is too
24 narrow in its scope and focus. The aim of the
25 rule should be expanded to reduce potential



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1 amplification of all TSEs and not focus so
2 narrowly on BSE. The first way in which it
3 should be modified is that there are too many
4 exclusions on the types of protein that are
5 regulated.

6 The second area where the rule
7 fails is that it does not sufficiently address
8 the potential for the transmission across
9 species barriers. These two failures will be
10 addressed below in response to Question 3.

11 Okay. So Question 3. TSEs
12 have been found to affect humans, goats, sheep,
13 mink, deer, elk, cattle, domestic and wild cats,
14 zoo ruminants and zoo primates. Experimentally,
15 TSEs have been transmitted to mice, and it has
16 also has been transmitted experiment to swine.
17 The transmissible agent for all TSEs is believed
18 to be an altered form of naturally occurring
19 protein -- prion -- that builds up in central
20 nervous tissue, leading to neurological disorder
21 and death.

22 In addition to being found in
23 the central nervous system, the transmissible
24 agent is also found in the lymphatic tissue,
25 intestines and blood. For each of the known



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1 TSEs, as FACT understands it, there is still
2 uncertainty about how the infectious agent is
3 transmitted and about how the disease develops
4 during incubation.

5 When interspecies transmission
6 is included, the picture becomes even murkier.
7 In the case of BSE, there is evidence of
8 transfer between cattle and many other species,
9 including felines, ruminants and humans. And in
10 these cases, this is natural transfer through
11 the world and not an experimental route. While
12 it is clear that there exist barriers to the
13 transmissions of TSEs between species, the
14 nature of these barriers is little understood.

15 Therefore, FACT urges the FDA
16 to limit the exclusion on mammalian proteins
17 allowed for feeding to ruminants to milk and
18 milk products and to products made exclusively
19 of horse and/or equine protein. The current
20 exclusion of blood products is unacceptable,
21 given the clear evidence of infectivity in
22 blood.

23 Similarly, there is no
24 justifiable reason to exclude food offered for
25 human consumption, such as plate waste. This is

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1 particularly important given the potential for
2 unspecified material of foreign origin in plate
3 waste such as was implicated in the outbreak of
4 foot-and-mouth disease in the United Kingdom.

5 Because of the continuing
6 evidence regarding the potential to transfer
7 TSEs between species, FACT recommends that the
8 FDA review whether or not restrictions should be
9 replaced on any animals with neurologic
10 disorders as feed for any livestock, including
11 poultry, equines and swine. The use of
12 materials from bovine central nervous system
13 should be banned, along with the use of bovine
14 materials from any countries with a high risk
15 for BSE for any animal feeding purposes.

16 In relation to Questions 4 and
17 5 on dedicated facilities or dedicated
18 transportation, FACT believes that dedicated
19 transportation and facilities are important,
20 given the very difficult task it would be to
21 enforce compliance or have inspection, on a
22 daily basis, of facilities. So you may come
23 once a year and look at the facilities and they
24 clean out very well; but cleaning out on a
25 day-to-day basis is going to be something that



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1 there will always be -- hides enough to cut
2 corners on that. So one way to get around that
3 strong incentive to cut corners on clean-out is
4 to just have dedicated facilities.

5 Okay. For Question 6. Where
6 FDA does not currently license feed preparation,
7 licensing other establishments would be an
8 excellent tool for increasing compliance with
9 the rule. If it is not feasible to license all
10 facilities, a subset of facilities could be
11 licensed. Facilities that produce feed for
12 ruminants could be licensed, or facilities that
13 handle both ruminant and non-ruminant feeds
14 could be licensed. Licensing would need to be
15 combined with enforcement to make it an
16 effective tool. Licensing combined with
17 monitoring using analytical methods that
18 distinguish between prohibited and
19 non-prohibited materials could provide a much
20 higher level of compliance than our current
21 system with its less than annual checks.

22 I'll skip down to Question 10.
23 Should FDA extend its present recordkeeping?
24 Records should be kept for a minimum of five
25 years. FACT pushed for this provision when the

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1 rule was first considered, and FACT still
2 believes it is an important provision. Because
3 the incubation period for BSE is four to five
4 years, FACT urges FDA to require that records be
5 kept for a minimum five years, providing the
6 information necessary to trace the source of
7 infection in case of an outbreak.

8 I am going to skip to Question
9 14. Regarding enforcing compliance with the
10 rule, what further authorities, if any, would be
11 desirable? FDA should use its existing
12 authority to condemn adulterated product as
13 defined in the rule in the case of repeated
14 consistent noncompliance. FDA should seek to
15 extend its authority to investigate potential
16 violations that occur where feed is mixed
17 on-farm. So FACT is concerned that there may be
18 mixing of ruminant proteins back on-farm that's
19 not inspected or monitored in any way
20 whatsoever. So we think there needs to be some
21 system to look at what's actually occurring
22 on-farm.

23 Regarding public and private
24 certification programs, our position basically
25 is that certification programs are fine as



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1 educational tools and to help businesses develop
2 their internal control systems, but they should
3 not be used by the FDA as a justification for
4 lessening its own compliance monitoring program.

5 On the importers of feed, FACT
6 urges the FDA to follow the official
7 International Des Epizooties standards and
8 conduct risk assessments on individual
9 countries. Given the risk of importing BSE
10 infected feed into the U.S., imported feed
11 containing animal proteins should not be used in
12 feeding ruminants unless the country of origin
13 has demonstrated effective rules for the
14 segregation and labeling of feed that are
15 equivalent to U.S. rules. So at this point,
16 since we don't have those risk assessments done,
17 I think we should be real cautious about any
18 imported feed for ruminants in the U.S. That's
19 a job that needs to be done.

20 Okay. Are there any other
21 additional measures necessary? FACT believes
22 that much more work needs to be carried out on
23 basic research on BSE and other TSEs. One area
24 that is absolutely essential is the development
25 of a diagnostic test that can be used on live

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1 animals. More research also needs to be done on
2 the nature of the species barriers between the
3 different TSEs. Right now we don't see any
4 evidence of there being a risk for a swine, but
5 I think that's something that we need to
6 constantly, in our minds, be alert for. We have
7 to remember that before BSE we didn't think
8 there was risk in bovines. Things change, so we
9 need to be very alert and careful.

10 In summary, FACT urges FDA to
11 continue its current efforts to control the
12 potential spread and amplification of BSE. In
13 addition, FACT calls on FDA to strengthen its
14 efforts by broadening the range of prohibited
15 products to include all ruminant proteins and by
16 taking further precautions with the most at-risk
17 materials, such as proteins from animals with
18 neurological disorders.

19 In the area of monitoring of
20 compliance, FDA needs to step up reinspection of
21 noncompliant firms and, if necessary, to use its
22 authority to condemn feed that is adulterated by
23 definition of the rule.

24 And again, I'd like to thank
25 FDA for providing us the opportunity to present

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1 these comments.

2 DR. LUMPKIN: Thank you, Mr.
3 Roach.

4 Are there any questions from
5 the panel?

6 I wasn't sure if you said this.
7 I apologize for having missed it. But does FACT
8 have any views on the poultry litter issue? You
9 talked about some of the exclusions. I wasn't
10 sure.

11 MR. ROACH: Yes, we do have a
12 concern there. I mean, our organization does
13 not believe that feeding litter is a good idea
14 for other issues. We think there's a big
15 problem with the drugs that pass through. BSEs,
16 we do think there's a risk, particularly from
17 spilled feed; but we think that there's the
18 other issues in terms of the feeding of blood
19 meal, and that is a much higher priority for our
20 organization.

21 DR. LUMPKIN: Thanks for
22 clarifying that.

23 We have now reached the point
24 in our agenda where we're supposed to have a
25 break until 3:00 when we will begin the time for

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1 individuals who did not register to talk. I'm
2 aware of one individual who has expressed a
3 desire to present to the panel, so I will
4 recognize that person at 3:00. If there are
5 others who are in the audience who wish to
6 speak, obviously they will be given an
7 opportunity following that individual.

8 So I will say, let's go for a
9 break, and we will reconvene at 3:00. Thanks
10 very much.

11 (A recess was taken.)

12 DR. LUMPKIN: It's a little
13 after 3:00, and to be fair to people who were
14 given time to talk, I would like to call us back
15 into session, please.

16 Before we get started, I would
17 simply like to point out for the record that
18 Dr. Dan Machesney has joined the panel as the
19 representative of the Center for Veterinary
20 Medicine at FDA. Dr. Sundlof had to return to
21 Washington early this afternoon and had to
22 leave.

23 As I mentioned before we took
24 our break, this is the time in the program that
25 it's been dedicated for testimony from other



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1 interested parties who did not register to speak
2 earlier today. I'm aware of one individual and
3 I'll call on that person now.

4 Chuck Massengill from the
5 National Cattlemen's Association.

6 MR. MASSENGILL: I'm Chuck
7 Massengill, a cattle producer from California,
8 Missouri. I'm on the National Cattlemen's Beef
9 Association, cattle health and well being
10 committee. I want to thank the agency for the
11 opportunity to respond verbally. We will have
12 detailed written response addressing each
13 individual item which will come prior to the
14 November 21st deadline. Thank you all very
15 much.

16 We asked for this time -- the
17 Cattleman's Beef Association asked for this time
18 to respond. We want to provide a very short
19 response, but we wanted to clearly reiterate the
20 basic position of the National Cattlemen's Beef
21 Association is that we feel that the rule as it
22 currently exists, with enforcement, is adequate
23 to continue to achieve the goal of preventing
24 the establishment and amplification of BSE in
25 the United States. We feel that any changes in

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1 this rule must be science-based, they must be
2 well documented, they must be well researched.
3 As so many people have repeated, there is so
4 much -- there are so many people with so much at
5 stake that it's just absolutely crucial that it
6 be a science-based program and continue that
7 way.

8 We see BSE as a foreign animal
9 disease. It's certainly one of several foreign
10 animal diseases that causes concern. We feel
11 specifically if the disease status of a country
12 is in question, we should stop trade with that
13 country and then ask questions and determine
14 what the actual risk is. We don't feel that we
15 should tarry in our decision to protect our
16 economy and our animal industry.

17 We encourage the agency to
18 continue to support research on means to exclude
19 BSE from the U.S.

20 That concludes my short
21 comments, sir.

22 DR. LUMPKIN: Thank you very
23 much.

24 Are there any questions for
25 Mr. Massengill?



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1 (No response.)

2 THE COURT REPORTER: Excuse me.
3 Would you spell your name for me, please?

4 MR. MASSENGILL:

5 M-a-s-s-e-n-g-i-l-l.

6 DR. LUMPKIN: The question was,
7 just for the record, for Mr. Massengill to spell
8 his name, since we didn't have it in writing for
9 the record.

10 I know there was some confusion
11 apparently earlier this morning about a comment
12 one of the speakers made, and so I will ask
13 Dr. Solomon to raise that question and the
14 speaker, my understanding is, will answer it.

15 DR. SOLOMON: Richard Sellers,
16 is he here?

17 The question that came up with
18 the comments you made about a submission of a
19 partnership agreement to the agency and
20 whether -- there was some confusion about the
21 status of that. If you'd clear that up.

22 MR. SELLERS: Sure, I'm happy
23 to clarify that. Yesterday we filed our
24 partnership agreement, and unless the acting
25 commissioner signed it yesterday, it's not been

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1 signed. It's a draft, and we expect to have
2 some negotiations. So it was filed yesterday.

3 DR. SOLOMON: It was a
4 petition, or how was that --

5 MR. SELLERS: It was a draft
6 partnership agreement with a letter accompanying
7 it asking the agency's participation.

8 DR. LUMPKIN: Thank you.

9 Is there anyone else at this
10 time who would like to speak before the panel
11 who did not register to do so?

12 (No response.)

13 DR. LUMPKIN: Going once, going
14 twice.

15 As I mentioned this morning, in
16 the Federal Register notice that announced this
17 meeting, we announced that the hour between four
18 and five would be held for public testimony if
19 people did not register to do so and wished to
20 do it. Under our rules of engagement, we indeed
21 have to be here at the beginning of that hour in
22 case someone looked at that in the register and
23 said "Oh, I need to be there at four in order to
24 say what I wanted to say before the panel." So
25 what I will do now is spend this meeting from



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1 now until four. We will reconvene at four to
2 check to see if, indeed, anyone is available,
3 anyone who wanted to talk at the appointed hour
4 in the FR notice. If there is no one here at
5 four, I will conclude the meeting at that
6 point.

7 So for right now the meeting is
8 suspended and we'll reconvene at four to make
9 that check.

10 (A recess was taken.)

11 DR. LUMPKIN: Ladies and
12 gentlemen, it's 4:00 by my watch. I'm calling
13 this hearing back into session.

14 The purpose of the hearing at
15 this point is to ask if there are any others who
16 did not register this morning who would like to
17 make comments before the panel. If they do,
18 please come forward now.

19 (No response.)

20 DR. LUMPKIN: Going once.
21 Going twice. Sold.

22 Okay. Thank you.

23 Before we close, I would like
24 to again thank our colleagues here in Kansas
25 City for the wonderful work they did to make



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1 this happen, to thank all of you who are still
2 here and have stayed with us all day and those
3 who chose to leave earlier for their comments.

4 With that, I declare this Part
5 15 hearing closed. Everybody have a safe trip
6 home.

7 (The proceedings concluded at
8 4:03 p.m.)
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Shorthand Reporter of the State of Kansas, do
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That I am not a relative or employee
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Linda R. Burt

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